

SUPPORTING STATEMENT FOR
MEDICAL DEVICES; MEDICAL DEVICE REPORTING:
MANUFACTURER REPORTING; IMPORTER REPORTING,
USER FACILITY REPORTING, DISTRIBUTOR REPORTING
0910-0437

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

FDA intends to issue a final rule (Tab A), which amends 21 CFR Part 803 and revokes Part 804 (Tab B) as required by sections 213 and 422 of the FDA Modernization Act of 1997 (FDAMA) (Tab C) and to otherwise revise the program as necessary. On May 12, 1998 (63 FR 26069), FDA issued a direct final rule to make these changes. FDA received significant adverse comment on the direct final rule and withdrew it on August 27, 1998 (63 FR 45716).

The revisions to 21 CFR Part 803 and revocation of Part 804 will eliminate MDR reporting requirements for distributors (who are not importers) of medical devices; eliminate annual certification requirements for manufacturers and distributors (including importers) of medical devices; and reduce the frequency of user facility summary reporting from semi-annual to annual.

For the sake of clarity, Part 803 will also be revised by transferring the MDR requirements for importers and other distributors of medical devices products from Part 804 to Part 803. The existing requirements relating to medical device distributors, including importers, became final by operation of law and was not part of the MDR final rule published on December 11, 1995 (60 FR 65397). The reporting and recordkeeping burdens attributed to distributors, including importers, were not considered in the OMB inventory for 0910-0059. Therefore, the reduction in overall burden is offset by an increase in the quantified burden on the current OMB inventory for 0910-0059 for requirements relating to distributors.

The information collection requirements contained in these regulations are as follows:

21 CFR 803.15 - Reporting

Section 803.15 provides that FDA may request a reporter to submit additional or clarifying information concerning an MDR report when FDA determines that additional information is necessary for the protection of the public health.

21 CFR 803.19 - Reporting

Under this rule, section 803.19 is modified to allow for importers of medical devices to request an exemption or variance from the reporting requirements. This modification does not represent

a change in burden; rather it is a transfer of provisions previously codified under section 804.33.

21 CFR 803.22(b)(2)

This final rule amends section 803.22(b)(2) to apply the same requirement to importers. The requirements of section 803.22(b)(2) were not previously reviewed by OMB under the PRA. Thus, the estimated burden reflects FDA's experience with this provision with regard to manufacturers and includes the estimated burden for both manufacturers and importers.

21 CFR 803.33 - Reporting

Under this rule, user facilities are required to submit summary reports annually. Previously, user facilities were required to submit reports semi-annually. Therefore, this information collection is reduced by half.

Consistent with the above revisions relating to user facility summary reporting, the FDA is seeking approval for modifications to FDA Form 3419 - User Facility Annual Report (Tab D)

21 CFR 803.40 - Reporting

This section requires importers of medical devices to submit MDR reports. This modification does not represent a change in burden; rather it is a transfer of provisions previously codified under section 804.25.

21 CFR 803.55 - Reporting

This section requires manufacturers to submit certain baseline information with their first MDR report and update the information annually. The information collection requirements in this section were approved under OMB no. 0910-0059. The approval, however, did not include FDA Form 3417 on which the information is to be submitted. This does not represent a change in burden. FDA is seeking approval of FDA Form 3417 (Tab E).

21 CFR 803.17 - Recordkeeping

Under this rule, section 803.17 is modified to require importers of medical devices to establish and maintain written procedures for documenting and processing MDR reports. This modification does not represent a change in burden; rather it is a transfer of provisions previously codified under section 804.34.

21 CFR 803.18 - Recordkeeping

Under this rule, section 803.18 is modified to require importers and other distributors of medical devices to establish and maintain MDR files. This modification does not represent a change in burden; rather it is a transfer of provisions previously codified under section 804.35.

2. By Whom and for What Purpose the Information is to be Used

Information from these reports will be used to evaluate risks associated with medical devices and to enable FDA to take appropriate regulatory measures to protect the public health.

3. Consideration of Information Technology

The final rule allows alternative appropriate technology in accordance with 21 CFR Parts 803.14. As such, reports can be electronically submitted with prior written consent from FDA.

4. Efforts to Identify Duplication and Similar Information Already Available

The FDA is the only Federal agency responsible for the collection of such information, and charged with the responsibility of regulating medical devices and establishments. Therefore, duplication with other data sources is nonexistent.

5. Small Businesses

The requirements set forth in the MDR regulation do not fall disproportionately upon small businesses. The threshold assessment conducted for this regulation shows that no more than 22 percent of the anticipated annual impact of these regulations should be attributed to small business establishments. The FDA continues to pursue ways and means of reducing the reporting burden for both small and large medical device manufacturers and will continue to employ the latest technology for receipt of reports, consistent with the intent of the MDR regulation and protection of the public health.

FDA aids small business by providing guidance and information through the Division of Small Manufacturers Assistance (DSMA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMA provides workshops, on-site evaluations and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. The Division also maintains a toll-free "800" telephone number which firms may use to obtain regulatory compliance information.

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles.

Section 213(c)(1)(A) of FDAMA revised section 519 (b)(1)(C) of the act to decrease frequency of user facility summary reporting from a semi annual to an annual basis. The frequency of other reporting, the frequency of which is unchanged by these amendments, is statutorily required under section 519 of the act.

7. Consistency with the Guidelines in 5 CFR 1320.5

This regulation is consistent with principles in 5 CFR 1320.5.

8. Consultation Outside the Agency

The Medical Device Reporting (MDR) regulations promulgated pursuant to the Safe Medical Devices Act of 1990 and the Medical Device Amendment of 1992 were finalized on December 11, 1995. Since that time, the agency has been in constant consultation with regulated industry regarding the MDR requirements. These amendments to the MDR requirements, required by FDAMA, reflect and respond to many of industry=s concerns. In accordance with 5 CFR 1320.8(d), on Tuesday May 12, 1998, in Volume 63, No. 91, page 26071, a 60-day notice for public comment Tab E) was published in the Federal Register. FDA received nine comments. A detailed discussion of the comments and FDA=s response is included in the preamble to the final rule.

Four comments objected that FDA did not follow the Congressional recommendation in the conference report on FDAMA that FDA limit the time that distributors be required to keep records to a maximum of six years. The direct final rule required that distributors keep records for two years or the expected life of the device, whichever is greater.

FDA carefully considered the recommendations of the conference committee. The agency determined that the protection of the public health would not be adequately served if distributor recordkeeping was limited to a period of six years. Under the new Quality System regulations contained in 21 CFR Part 820, manufacturers (including initial distributors of foreign manufacturers) must retain records for a period equal to the design and expected life of the device (but no less than two years). The agency believes it is appropriate to require distributors to retain records for the same time period. This is especially important because distributors are no longer required to report any adverse event information to the agency, and the agency=s primary access to the distributor complaint information is its periodic inspection and examination of the distributor records.

FDA considered electronic retention of distributor records. Prior to FDAMA and the proposed rule, the agency had not prohibited the electronic retention of records, nor did it intend to prohibit electronic recordkeeping based upon the proposal. When the distributor recordkeeping requirements were shifted from Part 804 to Part 803, the language remained largely unchanged. However, in order to avoid further confusion regarding electronic retention of records, the agency is modifying proposed section 803.18(d)(1) to clarify that distributor records may be either written or electronic.

Three comments stated that it is inappropriate to refer to the Quality Systems Regulation (21 CFR 820.198) in describing distributor recordkeeping because section 820.198 does not apply to distributors.

FDA agrees and has revised section 803.18(d) accordingly to remove the reference to

section 820.198. FDA is substituting language to identify the relevant requirements from section 820.198 that apply to distributors who are not importers. FDA notes, however, that section 820.198 does apply to importers of devices.

Two comments suggested that the reporting timeframe for importers should be changed to 30 days from 10 days.

FDA agrees with these comments and has revised the final rule. Previously, importers were included in part 804 with the reporting requirements for distributors. Because distributors are no longer required to report, part 804 is eliminated and importers are included in part 803 with manufacturers. The 30-day timeframe is consistent with the timeframe for manufacturers.

One comment suggested that the form for reporting adverse events (FDA Form 3500A) should be revised to refer specifically to importers. Another comment asked for clarification as to whether a person who sells directly to the ultimate user may be considered an Aimporter.

The agency agrees that the fields to be filled out by importers on FDA Form 3500A should be specified within the regulation. Because the requirements and burdens would not be affected by revising the style and format of section 803.43, the agency is modifying the section to be consistent with sections 803.32 and 803.52, which describe the information to be submitted on the MEDWATCH form.

The agency notes that, because Adistributors had previously been defined to include Aimporters, FDA Form 3500A does not specifically address importer information and does not use the term, Aimporters. However, block F of the MEDWATCH form is identified for use by device user facilities and distributors. An importer should continue to complete blocks A,B,D, E and F until the form is revised to remove references to Adistributor and replace them with Aimporter. The agency clarifies that firms who purchase products from a foreign manufacturer and sell directly to the ultimate user are considered retailers and not importers under part 803 and are not required to report.

One comment suggested that distributor reporting is important for the protection of the public health and recommended that, as an alternative to distributor reporting, FDA should require manufacturer contact information on the labeling to assure proper adverse event reporting.

The agency agrees that consumers are likely to contact medical device distributors with their device complaints. Without distributor reporting, it is possible that the agency will not receive information regarding some complaints. However, under FDAMA, the agency no longer has the authority to require distributor reporting. Although FDA cannot require distributor reporting, FDA encourages distributors to report adverse event information to manufacturers so that they may investigate and report it as appropriate. The suggestion that FDA require manufacturer contact information on the labeling is beyond the scope of this rule and FDA will consider it separately.

One comment objected that FDA incorrectly interpreted section 422 of FDAMA regarding the regulation of tobacco products, tobacco ingredients and tobacco additives. The

comment stated that section 422 only means that nothing in FDAMA shall affect whether FDA has the authority to regulate tobacco products. The comment further said that section 422 does not mean, as FDA believes, that the requirements, such as MDR reporting, for manufacturers and distributors of tobacco products are unchanged by FDAMA.

The agency disagrees with this comment. Section 422 of FDAMA states that ANothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive.≡ Although this language may suggest that FDAMA is simply silent regarding the agency=s authority to regulate tobacco, section 422 goes on to state that ASuch authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this act.≡ Beyond the question of whether the agency has authority to regulate tobacco, this language directs the agency as to how it should exercise such authority once pending litigation is resolved.

Under section 422, therefore, Congress neither affirms nor denies the agency=s authority to regulate tobacco, but it does direct the agency to continue regulating tobacco as it had been doing prior to FDAMA (if authority to regulate tobacco exists). Prior to FDAMA, distributor reporting and manufacturer and distributor certification were required under the act. If the agency were to exercise its authority under the act Aas in effect on the day before the date of the enactment of [FDAMA],≡ distributor reporting and manufacturer and distributor certification requirements would continue to apply to manufacturers and distributors of cigarettes and smokeless tobacco products.

However, while the agency disagrees with the comment=s interpretation of section 422 of FDAMA, FDA finds persuasive the comment=s arguments that tobacco manufacturers should be exempt from the requirement of annual certification of MDRs and that distributors should be exempt from MDR reporting requirements under the residual authority of the act. The agency has authority under section 519(c) of the act to exempt, by regulation, any person from the medical device reporting requirements upon a finding that such reporting is not necessary to Aassure that a device is not adulterated or misbranded or . . . otherwise to assure its safety and effectiveness.≡ 21 U.S.C. 360i(c). The agency finds that the statutory criteria for exemption are met in light of the fact that Congress has repealed the requirements for manufacturer and distributor annual certification and distributor reporting. A reasonable assurance of the safety and effectiveness of tobacco products will be provided by the remaining medical device reporting requirements, that is, reporting and record keeping required of manufacturers and importers and record keeping required of distributors.

9. Payments or Gifts to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Confidentiality of Information

Information contained in the information collections are available as described by 21 CFR 803.9, as amended. FDA may disclose the identity of a device user facility only in connection with an action concerning a failure to report or false or fraudulent reporting, in a communication to the manufacturer of the device, or to the employees of the Department of Health and Human Services, the Department of Justice, and duly authorized committees and subcommittees of Congress.

11. Sensitive Questions

The information collection does not include questions concerning sex, behavior, attitudes, religious beliefs, or private matters.

12. Estimates of Burden Hours and Explanation

The following is a summary of the estimated annual burden hours for medical device manufacturers, distributors, importers, and user facilities to report in compliance with the provisions imposed by this rule:

FDA estimates the burden of this collection of information as follows:

Table 1--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.15	50	1	50	4	200
803.19	150	1	150	3	450
803.22(b)(2)	100	1	100	.25	25
803.33 FDA Form 3419	1,800	1	1,800	1	1,800
803.40	195	1	195	3	585
803.55 FDA Form 3417	1,000	20	20,000	1.1	22,000
Total					25,060

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
803.17	2,000	1	2,000	3.3	6,600
803.18	39,764	1	39,764	1.5	59,646
Total					66,246

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burdens under this direct final rule are explained as follows:

Reporting Requirements

Prior to the program change reflected in this rule, distributors (including importers) were required to submit supplemental information under § 804.32. Distributors (who are not importers) are no longer required to submit MDR reports (including supplemental reports), and FDA has determined that it will not be necessary for importers to submit supplemental information except when FDA requests additional information under § 803.15. FDA has revised the final rule accordingly. Section 803.15 provides that FDA may request a reporter to submit additional or clarifying information concerning MDR report when FDA determines that additional information is necessary for the protection of the public health. The burden estimate for this section includes only the burden for importers.

Prior to the program change reflected in this rule, § 803.19 allowed manufacturers or user facilities to request an exemption or variance from the reporting requirements. The agency had estimated that it would receive approximately 100 such requests annually. Distributors (including importers) were able to request an exemption or variance from the reporting requirements under § 804.33. Under this rule, § 803.19 is modified to transfer the exemption provisions for importers of medical devices from § 804.33 to § 803.19. Furthermore, distributors (who are not importers) of medical devices are no longer required to submit MDR reports under this rule. The estimated burden for § 803.19 is further adjusted to reflect the agency's actual experience with this type of submission.

Prior to the program change reflected in this rule, section 803.22(b)(2) provided that, if a manufacturer erroneously receives information about an adverse event concerning a device that they had not manufactured, the manufacturer must submit the report to FDA along with a cover letter explaining that the device in question was not manufactured by that firm. This final rule amends section 803.22(b)(2) to apply the same requirement to importers. The requirements of section 803.22(b)(2) were not previously reviewed by OMB under the PRA. Thus, the estimated

burden reflects FDA=s experience with this provision with regard to manufacturers and includes the estimated burden for both manufacturers and importers.

Prior to the program change reflected in this rule, § 803.33 required medical device user facilities to submit summary reports semiannually. Under this rule, user facilities are required to submit summary reports annually, thereby significantly decreasing the reporting burden on user facilities. The estimated burden for this section is also adjusted to reflect the agency's actual experience with this type of submission. FDA Form 3419 is being revised to reflect this change.

Under this rule the reporting requirement for importers of medical devices previously codified under § 804.25 is being transferred to § 803.40. The estimated burden for importer reporting is based upon the agency's actual experience with this type of submission. Section 803.40 requires importers to submit reports within 30 days after learning of the reportable event rather than 10 days as provided in Sec 804.25; this change does not affect the burden.

This rule does not amend § 803.55 but FDA is seeking approval for FDA Form 3417 on which baseline reports are to be submitted. The agency=s estimate is based on FDA=s actual experience with this type of submission.

Prior to the program change reflected in this rule, § 803.57 required medical device manufacturers to annually certify as to the number of reports submitted during the previous year, or that no such reports had been submitted. Distributors (including importers) were required to certify under § 804.30. As stated above, FDA is also exempting manufacturers and distributors of cigarettes and smokeless tobacco products from the requirement of annual certification. Therefore, under this rule, § 803.57 and 804.30 are being eliminated.

Because distributors, including distributors of cigarettes and smokeless tobacco products, will no longer be required to report, the final rule also deletes sections 804.25 (Distributor reporting), 804.32 (Supplemental information), and 804.33 (Alternative reporting requirements).

Recordkeeping Requirements

Prior to the program change reflected in this rule, § 803.17 required manufacturers and user facilities to establish written procedures for employee education, complaint processing, and documentation of information related to MDR's. Under this rule, the requirements for establishing written MDR procedures for importers of medical devices have been transferred to § 803.17. The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information related to MDR reporting as part of their internal quality control system. The agency has estimated that no more than 2,000 such entities would be required to establish new procedures, or revise existing procedures, in order to comply with this provision. For those entities, a one-time burden of 10 hours, annualized over a period of 5 years, is estimated for establishing written MDR procedures. The remainder of manufacturers, user facilities, and importers not required to revise their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered "usual and customary" under 5 CFR 1320.3(b)(2).

Prior to the program change reflected in this rule, § 803.18 required manufacturers and user

facilities to establish and maintain MDR event files. Distributors (including importers) were required to establish and maintain MDR event files under § 804.35. Under this rule, § 803.18 is modified to transfer the recordkeeping requirements for importers and other distributors of medical devices including cigarettes and smokeless tobacco products from § 804.35 and section 804.35 is deleted. As discussed above, this recordkeeping may be done in an electronic format.

Under the proposed rule, distributors of cigarettes and smokeless tobacco products would have been required to establish written internal procedures for evaluating and reporting events. Because distributors of cigarettes and smokeless tobacco products will not be required to report under the final rule, section 804.34 is deleted from the final rule.

Cost to Manufacturers and Importers:

Manufacturers of medical devices other than cigarettes or smokeless tobacco products will no longer be required to annually certify as to the number of MDR reports submitted during the previous year. The original Threshold Assessment for MDR identified the cost burden of manufacturer certification to be \$316 thousand, or approximately \$26 per manufacturer. Under this rule, manufacturers and importers of cigarettes or smokeless tobacco products will continue to annually certify, thus there will be a continued cost burden of \$806. This will reduce the annual cost burden for manufacturers and importers by 315,194 below the cost burden previously approved under 0910-0059.

Cost to User Facilities:

The original Threshold Assessment for MDR identified the cost burden of semi-annual reporting to be \$59 thousand. This rule reduces the frequency for summary reporting to annually, reducing the annual cost by half. The agency therefore attributes to this rule, a cost of \$29,500 for user facilities.

13. Annual Costs to Respondents

Because this rule imposes no new additional responsibilities on respondents, no capital or operational expenses are expected as a result of this rule.

14. Government Costs:

Because this rule does not require the processing of any additional reports by the government, no additional costs to the government will be incurred as a result of this rule.

15. Changes in Burden

This rule will create an increase of 42,000 burden hours and \$49 thousand over the current inventory approved under 0910-0059. This increase represents the inclusion of the current distributor reporting requirements not previously considered under 0910-0059. The increase also

reflects an adjustment to the agency=s burden estimates based upon its experience with MDR.

16. Statistical Reporting

No publication of information for statistical use is planned.

17. Exemption for Display of Effective Date

FDA is not seeking an exemption of display of effective date.

18. Exception to Certification Statement

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I.

List of Attachments:

Tab A - Medical Device Reporting; Final Rule

Tab B - 21 CFR Parts 803 and 804

Tab C - FDAMA, sections 213 and 422

Tab D - User Facility Annual Report form FDA 3419

Tab E - Baseline Report FDA Form 3417